REMARKS

A. BACKGROUND

The present Amendment is in response to the Office Action mailed October 1, 2009. Claims 1-6, 9-12, 15, 16, and 21-27 were pending and rejected in view of cited art. Claims 1, 5-6, 9, 11, 12, 15-16, 23, and 25 are amended, claims 4 and 10 are canceled, and claim 28 is added. Claims 1-3, 5-6, 9, 11-12, 15-16, and 21-28 remain pending in view of the above amendments, with claims 1 and 23 being independent.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, are consistent with the Examiner's understanding.

B. PRIOR ART REJECTIONS

I. REJECTION UNDER 35 U.S.C. § 103

The Office Action rejected claims 1-4, 9, 10, 21-26, and 27 under 35 U.S.C. § 103(a) as being unpatentable over European Patent No. EP1132059 (*Johnson*) in view of U.S. Patent No. 5,295,959 (*Gurbel*), U.S. Patent No. 6,161,029 (*Spreigl*), U.S. Patent No. 6,238,430 (*Klumb*), U.S. Patent No. 5,242,451 (*Harada*), U.S. Patent No. 4,886,062 (*Wiktor*). Claims 5, 6, 11, 12, 15, and 16 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the previous combination of *Johnson* in view of *Gurbel*, *Spreigl*, *Klumb*, *Harada*, and *Wiktor*, as applied to claims 1, 4, and 23, and further in view of U.S. Patent No. 5,308,356 (*Blackshear*).

Johnson was cited as disclosing "folding a balloon into a number longitudinal pleats . . . , placing the balloon into a mold, and pressurizing and heating the mold . . . to create protrusions in any area where the balloon is not compressed with a phantom stent" (Office Action, page 2). The method associated with forming the "phantom stent" is "similar" to that described with other

configurations of the balloon catheter of *Johnson*. (See para. [0040]). In one particular configuration that utilizes a stent, "[t]he balloon is folded into any suitable or preferable number of longitudinal pleats which are wrapped around a portion of the catheter shaft" (Para. 0031). "[A] stent is slipped onto the pleated balloon . . . [and] then gently crimped or compressed around the balloon" (Para. 0032). "[T]he resultant balloon catheter and stent assembly is then placed in a tubular mold" (Para. 0033). "The balloon is then pressurized by applying a pressurized fluid to the inflation port" and "the mold with accompanying balloon catheter and stent assembly . . . are held in a hot box or heated die" (Para. 0035 and 0036).

Johnson neither teaches nor suggests that the protrusions are formed "following folding the balloon after removing the balloon from the mold" as recited in independent claims 1 and 23 or "attaching the balloon to a balloon catheter" after the protrusions are formed, with the balloon subsequently receiving the stent as recited in independent claim 23. Rather, *Johnson* teaches forming the distal and proximal shoulders through pressurization of the balloon within a mold, with subsequent heating. Independent claims 1 and 23 recite that the wrapped member is applied "following folding the balloon after removing the balloon from the mold."

Grubel teaches a molding process similar to *Johnson* in that "the balloon can be wrapped with a band . . . prior to heat treatment in inflated condition in a conventional mold in order to set into the walls thereof preformed channels" (*Grubel*, col. 6, ll. 32-35). *Grubel* also describes (i) securing a compression band to the balloon to create the fluid channels or (ii) introducing the channels into the outer surface "during conventional thermoplastic molding processing" (see col. 6). *Grubel* fails to overcome the deficiency of *Johnson*. No mention is made in *Grubel* of protrusions being formed "following folding the balloon after removing the balloon from the mold" as recited in independent claims 1 and 23 or "attaching the balloon to a balloon catheter" after the protrusions are formed, with the balloon subsequently receiving the stent as recited in independent claim 23.

With respect to *Blackshear*, it was cited as disclosing "that one well known method of making a balloon catheter is to introduce a tube into a mold and inflate the tube into the shape of the balloon" (Office Action, pg. 5). *Blackshear* teaches

> "inflating a small tube in a heated mold lends itself readily to the fabrication of the wrinkled, grooved balloons of the invention. The mold is fabricated to form wrinkles opened to half their full extent. Suction, then, will produce the minimum profile with the wrinkles exhibiting a bending moment while full inflation will produce the open wrinkles, also under stress but with less

strain than if the wrinkles had been blown in the collapsed configuration." (Col. 6, ll. 41-50)

Blackshear also fails to overcome the deficiency of *Johnson*. No mention is made in *Blackshear* of protrusions being formed "following folding the balloon after removing the balloon from the mold" as recited in independent claims 1 and 23 or "attaching the balloon to a balloon catheter" after the protrusions are formed, with the balloon subsequently receiving the stent as recited in independent claim 23.

In view of the above, Applicant traverses the Examiner's rejection for obviousness on the grounds that the references[1] – either individually or in combination – fail to teach or suggest each and every element of the rejected claims. In view of the above, Applicant respectfully requests withdrawal of rejection of claims 1-3, 5-6, 9, 11-12, 15-16, and 21-28 under Section 103.

C. CONCLUSION

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

[1] *Spreigl*, *Klumb*, *Harada*, and *Wiktor* were cited as providing evidence of "stents with a plurality of apertures between adjacently spaced loops in the stents" being well known art. Applicant respectfully submits that *Spreigl*, *Klumb*, *Harada*, and *Wiktor* also fail to overcome the deficiencies of *Johnson* described herein because no mention is made in the references of protrusions being formed "following folding the balloon after removing the balloon from the mold" as recited in independent claims 1 and 23 or "attaching the balloon to a balloon catheter" after the protrusions are formed, with the balloon subsequently receiving the stent as recited in independent claim 23.

Dated this 29th day of January, 2010.

Respectfully submitted,

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